7. A method for expressing a transgene in a skeletal muscle cell in the absence of a cytotoxic immune response directed against the cell, comprising the step of introducing into the cell a recombinant adeno-associated virus (rAAV) comprising a transgene operably linked to sequences which control its expression, wherein the rAAV is substantially free of contamination with a helper virus and wherein the transgene is expressed in the cell.

16. A recombinant adeno-associated virus (AAV) comprising (a) 5' AAV inverted terminal repeats (ITRs), (b) a minigene comprising sequences encoding human apolipoprotein E (ApoE) under the control of sequences which direct its expression in a host cell, and (c) 3' AAV ITRs.

17. The recombinant AAV according to claim 16, wherein the minigene comprises a promoter.

18. The recombinant AAV according to claim 17, wherein the promoter is an inducible promoter.

19. The recombinant AAV according to claim 17, wherein the promoter is a constitutitive promoter.

20. The recombinant AAV according to claim 19, wherein the promoter is selected from the cytomegalovirus immediate early promoter and the Rous sarcoma virus LTR promoter.

21. A composition comprising a recombinant AAV according to claim 16 and a biologically compatible solution.

22. The composition according to claim 21, wherein said composition comprises at least 10^9 particles rAAV.

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PENDING CLAIMS

1 (Twice Amended). A method of delivering a selected transgene to an animal comprising the step[s] of administering a recombinant adeno-associated (rAAV) comprising [a] the selected transgene operably linked to sequences which control expression thereof [and administering the rAAV] to the animal intramuscularly, wherein said rAAV is substantially free of contamination with a helper virus.

2. The method according to claim 1 wherein said muscle is selected from the group consisting of skeletal muscle, cardiac muscle and smooth muscle.

3. The method according to claim 1 wherein the selected transgene encodes a secretable protein.

4. The method according to claim 3 wherein said protein is selected from the group consisting of Factor IX, ApoE, β-interferon, insulin, erythropoietin, growth hormone, and parathyroid hormone.

5. The method according to claim 1 wherein the recombinant AAV further comprises AAV 5' and 3' inverse terminal repeats (ITRs) flanking the transgene.

(A) 6 (Amended) The method according to claim 5 wherein the recombinant AAV consists essentially of from 5' to 3', a 5' AAV ITR, a cytomegalovirus promoter, ~~a selected~~ the transgene, a polyadenylation sequence, and a 3' AAV ITR.

Cancel 7. The method according to claim 1 wherein the transgene is a dystrophin gene.

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8 (Amended). A method of treating [an animal] a patient with hemophilia comprising [the method of] administering into the muscle of the [animal] patient, at a level which provides a therapeutic effect, a recombinant adeno-associated virus comprising the gene for factor IX and regulatory sequences capable of directing expression of said gene.

9 (Amended). A method of treating [an animal] a patient with atherosclerosis comprising [the method of] administering into the muscle of the [animal] patient, at a level which provides a therapeutic effect, a recombinant adeno-associated virus comprising the gene for ApoE and regulatory sequences capable of directing expression of said gene.

(A) 20. The method according to claim 1, wherein the rAAV comprises a constitutive promoter. (Amended) any of to 6, 8, 9, 24, or 25

21. The method according to claim 20, wherein the constitutive promoter is selected from the group consisting of the cytomegalovirus immediate early promoter, and the Rous sarcoma LTR promoter.

(A) 22. (Amended) The method according to any of claim 1, wherein the rAAV comprises an inducible promoter. to 6, 8, 9, 24 or 25

(A) 23. (Amended) The method according to any of claim 1, wherein the rAAV is substantially free of contamination with adenovirus or wild-type AAV. 8, 9, 24, or 25

24 (Amended). A method of delivering Factor IX to [an animal] a patient comprising the step[s] of introducing into the muscle of the patient a recombinant adeno-associated virus (rAAV) comprising a [selected] transgene encoding Factor IX operably linked to sequences which control expression thereof.

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25. The method according to claim 24, wherein said rAAV is substantially free of contamination with a helper virus.

26. A method of delivering apolipoprotein E (ApoE) comprising the step of introducing into the muscle of a patient a recombinant adeno-associated virus (rAAV) comprising a selected transgene encoding ApoE operably linked to sequences which control expression thereof.